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Ridgefield, CT 06877

In re: Patent Term Extension
Application for
U.S. Patent No. 5,852,195

NOTICE OF FINAL DETERMINATION

A determination has been made that U.S. Patent No. 5,852,195, which claims the human drug product APTIVUS®, is eligible for patent term extension under 35 U.S.C. § 156. The period of extension has been determined to be 1278 days.

A single request for reconsideration of this final determination as to the length of extension of the term of the patent may be made if filed within one month of the date of this notice. Extensions of time under 37 CFR § 1.136(a) are not applicable to this time period. In the absence of such request for reconsideration, the Director will issue a certificate of extension, under seal, for a period of 1278 days.

The period of extension, if calculated using the Food and Drug Administration determination of the length of the regulatory review period published in the Federal Register of September 20, 2006 (71 Fed. Reg. 54995), would be 1279 days. Under 35 U.S.C. § 156(c):

Period of Extension (not considering the 14 year limitation of 35 U.S.C. § 156(c)(3))

$$\begin{aligned} &= \frac{1}{2} (\text{Testing Phase}) + \text{Approval Phase} \\ &= \frac{1}{2} (2931 - 739) + 183 \\ &= \frac{1}{2} (2193) + 183 \\ &= 1096 + 183 \\ &= 1279 \text{ days (3.5 years)} \end{aligned}$$

Since the regulatory review period began December 14, 1996, before the patent issued (December 22, 1998), only that portion of the regulatory review period occurring after the date the patent issued has been considered in the above determination of the length of the extension period in accordance with 35 U.S.C. § 156(c). (From December 14, 1996 to and including December 22, 1998 is 739 days; this period is subtracted from the number of days occurring in the testing phase according to the FDA determination of the length of the regulatory review period.) No determination of a lack of due diligence under 35 U.S.C. § 156(c)(1) was made.

However, the 14 year exception of 35 U.S.C. § 156(c)(3) operates to limit the term of the extension in the present situation because it provides that the period remaining in the term of the patent measured from the date of approval of the approved product plus any patent term extension cannot exceed fourteen years. The period of extension calculated above, 1279 days, would extend the patent from December 22, 2015 to June 23, 2019, which is beyond the 14-year limit (the approval date is June 22, 2005, thus the 14 year limit is June 22, 2019). The period of extension is thus limited to 1278 days, by operation of 35 U.S.C. § 156(c)(3). Accordingly, the period of extension is the number of days to extend the term of the patent from its original expiration date, December 22, 1998, to and including June 22, 2019, or 1278 days.

The limitations of 35 U.S.C. 156(g)(6) do not operate to further reduce the period of extension

determined above.

Upon issuance of the certificate of extension, the following information will be published in the Official Gazette:

U.S. Patent No.:	5,852,195
Granted:	December 22, 1998
Original Expiration Date ¹ :	December 22, 2015
Applicant:	Romines, et al.
Owner of Record:	Pharmacia & Upjohn Company LLC
Title:	Pyranone Compounds Useful to Treat Retroviral Infections
Product Trade Name:	APTIVUS®
Term Extended:	1278 days
Expiration Date of Extension:	June 22, 2019

Any correspondence with respect to this matter should be addressed as follows:

By mail:	Mail Stop Hatch-Waxman PTE	By FAX:	(571) 273-7754
	Commissioner for Patents		
	P.O. Box 1450		
	Alexandria, VA 22313-1450.		

Telephone inquiries related to this determination should be directed to the undersigned at (571) 272-7754.



Kathleen Kahler Fonda
Legal Advisor
Office of Patent Legal Administration
Office of the Deputy Commissioner
for Patent Examination Policy

cc: Office of Regulatory Policy
HFD - 7
5600 Fishers Lane (Rockwall II Rm. 1101)
Rockville, MD 20857

Attention: Beverly Friedman

Re: APTIVUS®
FDA Docket No.: 2006E-0033

¹Subject to the provisions of 35 U.S.C. § 41(b).